DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 19 '01 MAY 24 P3:37

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for a revised withdrawal time for use of oxytetracycline hydrochloride soluble powder in drinking water of swine.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7580.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed a supplement to NADA 8–622 that provides for use of TERRAMYCIN® (oxytetracycline hydrochloride) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental NADA provides for a zero-day slaughter withdrawal time after the use of the product in drinking water of swine. The application is approved as of April 25, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (d)(1)(iii)(C) by removing "Nos. 000069 and 059130" and by adding in its place "No. 059130 and zero days those products sponsored by No. 000069".

Dated: MAY 16, 2001
May 16, 2001.

Claire M. Lathers,
Director,
Office of New Animal Drug Evaulation,
Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S